Purged
HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

5149

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

January 29, 2001

WARNING LETTER

NWE-10-01W

VIA FEDERAL EXPRESS

Mr. Perry Russo, Co-Owner
Cracovia Company, LLC
735 Canal Street, Building 15 Rear
Stamford, CT 06902

Dear Mr. Russo:

We inspected your firm, located at 735 Canal Street, Building 15 Rear, on November 20-21, and 27, 2001, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your hermetically sealed and smoked, vacuum-packed seafood products to be in violation of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act. You can find this Act and the seafood HACP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

As a Domestic Processor:

- You must have a HACCP Plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (c) (1). However, your firm's HACCP Plan for Herring Fillets in Wine, European Thick Cut Herring Fillets, Rollmops Herring, Bismarck Herring, Whole Mackerel, Mackerel Fillets, Mackerel Fillets Spice, White Fish, Rainbow Trout, Herring Rollmop Pail, Smoked Eel, Chubs, and Smoked Sprats does not list the food safety hazard of pathogen growth at the Receiving and Refrigerated Storage Critical Control Points.

- You must implement the record keeping system listed in your HACCP Plan, to comply with 21 CFR 123.6 (b). However, your firm did not record monitoring observations at the Receiving Critical Control Point to control the hazard of *Clostridium botulinum* listed in your HACCP Plan; nor did your firm record monitoring observations at the Refrigerated Storage Critical Control Point after 4/01/00 to control the hazard of *Clostridium botulinum* listed in your HACCP Plan.

As an Importer:

- There are no written product specifications for seafood products imported from Canada, to comply with 21 CFR 123.12 (a) (2) (i).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a revised HACCP Plan, examples of monitoring records at receipt and storage that you have resumed keeping, and a copy of the written product specifications you have compiled for seafood products imported from Canada. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, and the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Stoneham, MA, 02180. If you have any questions regarding any issue in this letter, please contact Mr. Ota at 781-279-1719.

Sincerely,

Gail T. Costello, Director
New England District Office